

### **III. REMARKS**

#### **A. Status of the Claims**

Claims 1, 9-12, 20 and 40-45 are currently pending. Claims 2-8, 13-19 and 21-39 have been cancelled without prejudice. Claims 1 and 9-11 have been amended. New claims 40-45 have been added. Support for the amendments to claims 1 and 9-11 and new claims 40-45 can be found, e.g., in the original claims as filed. It is respectfully submitted that no new matter has been added by virtue of this amendment.

#### **B. Objections to the Disclosure**

In the Office Action, the Examiner made objections to the abstract of the disclosure for containing legal terminology. The Examiner also objected to the specification, stating that the priority information needed to be updated and spelling and punctuation errors needed to be corrected.

In response, Applicants have amended the disclosure to address the Examiner's comments.

#### **C. Claim Rejections Under 35 U.S.C. § 112**

In the Office Action, the Examiner rejected claims 13, 14, 18, 22, 27 and 34 under 35 U.S.C. § 112, second paragraph.

As claims 13, 14, 18, 22, 27 and 34 have been cancelled, this rejection is now moot and the Examiner is requested to remove the rejections.

#### **D. Double Patenting Rejections**

In the Office Action, the Examiner rejected claims 1-4, 6, 10 and 15-36 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,716,449.

This rejection is traversed. Applicants note that the '449 patent recites claims directed to transdermal dosage forms. It is respectfully submitted that the claims of the '449 do not teach or suggest the presently claimed solid, oral controlled-release dosage form. Accordingly, the Examiner is requested to remove the double patenting rejection over the '449 patent.

The Examiner rejected claims 1-5, 10, 11, 15, 16, 19, 21, 23, 24, 26, 32 and 33 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32, 34-37 and 39-44 of co-pending application no. 10/199,972.

Applicants note that claims 9 and 18 were not included in the double patenting rejection over the '972 application and the limitations of these claims have been incorporated into independent claim 1. Accordingly, the Examiner is requested to remove the double patenting rejection over the '972 application.

The Examiner rejected claims 1-5, 16-19, 21-23, 26-28, 33 and 34 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32, 34-37 and 39-44 of co-pending application no. 10/214,413.

Applicants note that claims 9 and 15 were not included in the double patenting rejection over the '413 application and the limitations of these claims have been incorporated into independent claim 1. Accordingly, the Examiner is requested to remove the double patenting rejection over the '413 application.

**E. Claim Rejections Under 35 U.S.C. § 102(b)**

In the Office Action, the Examiner rejected claims 1, 4, 5, 9, 15-17, 19 and 20 under 35 U.S.C. § 102(b) as being anticipated by WO 99/32120.

Applicants note that claims 2, 3 and 18 were not included in the anticipation rejection over WO 99/32120 and the limitations of these claims have been incorporated into independent claim 1. Accordingly, the Examiner is requested to remove the anticipation rejection over WO 99/32120.

**F. Claim Rejections Under 35 U.S.C. § 103(a)**

In the Office Action, the Examiner rejected claims 2, 18, 21-30 and 33-36 under 35 U.S.C. § 103(a) as being obvious over WO 99/32120 as applied against claims 1, 4, 5, 9, 15-17, 19 and 20 above, and further in view of Crain et al., U.S. 5,767,125.

Applicants note that claim 3 was not included in the obviousness rejection over WO 99/32120 in view of Crain et al., and the limitation of this claim has been incorporated into independent claim 1. Accordingly, the Examiner is requested to remove the obviousness rejection over WO 99/32120 in view of Crain et al.

The Examiner rejected claims 3 and 10-14 under 35 U.S.C. § 103(a) as being obvious over WO 99/32120 as applied against claims 1, 4, 5, 9, 15-17, 19 and 20 above, and in further view of WO 00/01377 or Simon, U.S. 6,103,258.

Applicants note that claims 2 and 18 were not included in the obviousness rejection over WO 99/32120 in view of WO 00/01377 or the Simon reference, and the limitations of these claims have been incorporated into independent claim 1. Accordingly, the Examiner is requested to remove the obviousness rejection over WO 99/32120 in view of WO 00/01377 or the Simon reference.

The Examiner rejected claims 31 and 32 under 35 U.S.C. § 103(a) as being obvious over WO 99/32120 in view of Crain et al. as applied against claims 2, 18, 21-30 and 33-36 above, and in further view of WO 00/01377 or Simon.

As claims 31 and 32 have been cancelled, this rejection is now moot and the Examiner is requested to remove the rejections.

**G. Claim Rejections Over Palermo et al.**

In the Office Action, the Examiner rejected claims 1, 4, 5, 9, 15-17, 19 and 20 under 35 U.S.C. § 102(e) as being anticipated by Palermo et al., U.S. 6,228,863; claims 2, 18, 21-30 and 33-36 under 35 U.S.C. § 103(a) as being obvious over Palermo et al. in view of Crain et al.; claims 3 and 10-14 under 35 U.S.C. § 103(a) as being obvious over Palermo et al. in view of WO 00/01377 or Simon.

Applicants note that claims 2, 3 and 18 were not included in the 102(e) rejection over the Palermo reference and the limitations of these claims have been incorporated into independent claim 1. Accordingly, the Examiner is requested to remove the 102(e) rejection over the Palermo reference.

Applicants note that claims 3, 5, 9, 15, 16 and 19 were not included in the obviousness rejection over the Palermo reference in view of Crain et al. and the limitations of these claims have been incorporated into independent claim 1. Accordingly, the Examiner is requested to remove the obviousness rejection over the Palermo reference in view of Crain et al.

Applicants note that claims 2, 5, 9, 15, 16, 18 and 19 were not included in the obviousness rejection over the Palermo reference in view of WO 00/01377 or Simon, and the limitations of these claims have been incorporated into independent claim 1. Accordingly, the Examiner is requested to remove the obviousness rejection over the Palermo reference in view of WO 00/01377 or Simon.

#### **H. Claim Rejections over WO 00/01377**

In the Office Action, the Examiner also rejected claims 1-4, 6, 10, 18-23, 26-28 and 32-34 under 35 U.S.C. § 103(a) as being obvious over WO 00/01377 in view of Reder et al., U.S. 5,968,547.

Applicants note that claims 5, 9, 15 and 16 were not included in the obviousness rejection over WO 00/01377 in view of Reder et al., and the limitations of these claims have been incorporated into independent claim 1. Accordingly, the Examiner is requested to remove the obviousness rejection over WO 00/01377 in view of Reder et al.

In the Office Action, the Examiner rejected claims 1-4, 7, 10, 18-23, 26-28 and 32-34 under 35 U.S.C. § 103(a) as being obvious over WO 00/01377 in view of Chasin et al., U.S. 5,942,241.

Applicants note that claims 5, 9, 15 and 16 were not included in the obviousness rejection over WO 00/01377 in view of Chasin et al., and the limitations of these claims have been incorporated into independent claim 1. Accordingly, the Examiner is requested to remove the obviousness rejection over WO 00/01377 in view of Chasin et al.

#### **I. Claim rejections over Simon**

In the Office Action, the Examiner rejected claims 1-4, 6, 10, 18-23, 26-28 and 32-34 under 35 U.S.C. § 103(a) as being obvious over the Simon reference in view of the Reder reference; and claims 1-4, 7, 10, 18-23, 26-28 and 32-34 under 35 U.S.C. § 103(a) as being obvious over the Simon reference in view of the Chasin reference.

Applicants note that claims 5, 9, 15 and 16 were not included in the obviousness rejection over the Simon reference in view of either the Reder reference or the Chasin reference, and the limitations of these claims have been incorporated into independent claim 1. Accordingly,

the Examiner is requested to remove the obviousness rejection over Simon reference in view of the Reder reference or the Chasin reference

**J. Information Disclosure Statement**

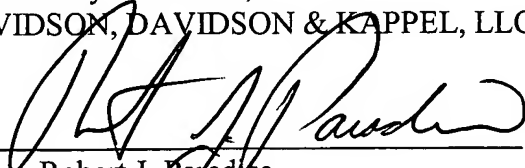
Applicants submit herewith copies of references listed as BR; DM-DR; EM-ES; FL-FR; GI-GO; HI-HO; IJ-IS; JI-JR; KI-KQ; LI-LS; MH-MP; NG-NN; OG-OO and RQ on the Form PTO-1449 filed September 7, 2004, which the Examiner indicated were not provided in the parent application. Also submitted herewith is an additional copy of the Form PTO-1449, listing only the references which have not been initialed by the Examiner.

**IV. CONCLUSION**

It is respectfully submitted that in view of the amendments made and the arguments presented, that this case is now in condition for allowance. An early and favorable action on the merits is earnestly solicited.

According to currently recommended Patent Office policy the Examiner is requested to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

Respectfully Submitted,  
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